

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and

Case No. 1:17-cv-00124-LLS

THE PEOPLE OF THE STATE OF NEW
YORK, by LETITIA JAMES, Attorney
General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited
liability company;

PREVAGEN, INC., a corporation
d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE
MANUFACTURING, LLC, a limited
liability company; and

MARK UNDERWOOD, individually and as
an officer of QUINCY BIOSCIENCE
HOLDING COMPANY, INC., QUINCY
BIOSCIENCE, LLC, and PREVAGEN,
INC.,

Defendants.

**PLAINTIFFS' SUPPLEMENTAL MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY OF
DRS. SCHWARTZ, KATZ, WEI, KURZER, GOODMAN, AND GORTLER,
AND IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE DR. BERG**

Plaintiffs, the Federal Trade Commission and the People of the State of New York by Letitia James, Attorney General of the State of New York, respectfully submit this supplemental briefing in support of the remaining portions of Plaintiffs' Motion to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler (filed Sept. 1, 2022) (ECF No. 303) and in opposition to the remaining portion of

Defendants' Motion to Exclude Experts (filed Sept. 1, 2022) (ECF No. 307) to the extent that it seeks to exclude the testimony of Plaintiffs' expert, Dr. Jeremy Mark Berg.¹ During the Final Pretrial Conference held on February 15, 2024, Defendants requested leave to submit additional briefing in support of their Motion to Exclude Dr. Berg's testimony in light of recent amendments to Rule 702 of the Federal Rules of Evidence. The recent amendments to Rule 702 did not substantively change the standard in effect at the time the parties submitted their motions to exclude expert testimony. Plaintiffs therefore submit that the Court already applied the appropriate standard in its December 19, 2022 Order (ECF No. 331). The amendments to Rule 702 should have no effect on the Court's rulings in that Order. The amendments merely underscore, as detailed below, that Plaintiffs have demonstrated by well more than a preponderance of the evidence that the testimony of Dr. Berg satisfies each of the requirements of Rule 702, while Defendants have failed to demonstrate, by a preponderance of the evidence, each of the Rule 702 requirements for the admissibility of their experts' testimony.

I. LEGAL STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

The admissibility standard for expert testimony is governed by Federal Rule of Evidence 702, which was amended in December 2023. The new language of Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training or education may testify in the form of an opinion or otherwise if **the proponent demonstrates to the court that it is more likely than not that:** (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to demonstrate a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's **opinion reflects a reliable application of the principles and methods to the facts of the case.**

¹ The Court has already ruled upon the portion of Defendants' Motion that sought to exclude the testimony of Plaintiffs' experts Drs. Mary Sano and Janet Wittes. Opinion & Order (filed Dec. 19, 2022) (ECF No. 331) at 17-18.

FED R. EVID. 702 (emphasis on new language added). This amendment does not reflect a substantive change to the Rule but merely serves to clarify the evidentiary standard because certain courts were applying it incorrectly.

The Federal Rules of Evidence Advisory Committee (“Committee”) explained that Rule 702 was amended to make clear that a proponent of an expert’s testimony must demonstrate to the court that an expert’s testimony meets a preponderance of the evidence standard, i.e., that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule. *See* FED R. EVID. 702 Advisory Committee’s Note to 2023 Amendment. Courts in the Second Circuit have long applied the proper preponderance standard, holding that “[w]hile the proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied, the district court is the ultimate ‘gatekeeper.’” *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007); *see also Arista Records LLC v. Usenet.com, Inc.*, 608 F. Supp. 2d 409, 422 (S.D.N.Y. 2009); *S.E.C. v. Tourre*, 950 F. Supp. 2d 666, 674 (S.D.N.Y. 2013). In *Tourre*, the Court stated:

To determine whether a proposed expert’s testimony passes muster under Rule 702, this Court must inquire into: (1) the qualifications of the proposed expert; (2) whether each proposed opinion is based upon reliable data and reliable methodology; and (3) whether the proposed testimony would be helpful to the trier of fact. The party seeking to introduce and rely on expert testimony bears the burden of establishing that the proposed expert and his or her testimony meets the requirements of Rule 702 by a preponderance of the evidence.

Tourre, 950 F. Supp. 2d at 674 (internal citations omitted).

Rule 702(d) was also amended to state a proponent must demonstrate to the court that it is more likely than not that “the expert’s opinion reflects a reliable application of the principles and methods to the facts of the case.” *See* FED R. EVID. 702(d). The Committee explains that this amendment serves to emphasize that expert opinions “must stay within the bounds of what can be concluded from a reliable application of the expert’s basis and methodology.” *See* FED R.

EVID. 702 Advisory Committee's Note to 2023 Amendment. The Committee details that judicial gatekeeping is necessary to ensure an expert is not providing an opinion or conclusion that go beyond what the expert's basis and methodology can reliably support. *Id.* This amendment does not impose any new, specific requirements and, instead, operates to prevent experts from making claims that are unsupported by the experts' bases and methodology. *Id.*

II. DR. BERG

Defendants are expected to incorrectly argue that Dr. Berg's testimony should be excluded in light of the amended standard laid out in Rule 702. Defendants' motion to exclude Dr. Berg's testimony was not granted previously, and should not be granted now. To the extent that the Court concludes that the Rule 702 amendments implement a higher standard than previously applied, Dr. Berg's proposed testimony meets all requirements for admissibility.

Plaintiffs have shown by a preponderance of the evidence that: (1) Dr. Berg has the appropriate expertise to opine on the digestion of apoaeguorin as well as Defendants' hypothesized mechanisms of action of apoaeguorin, the primary ingredient in Prevagen; (2) his opinions are based on reliable scientific principles and methods; (3) his principles and methods have been applied reliably to Prevagen and the other facts of this case; and (4) his opinion will assist the trier of fact, thus satisfying each of the prongs of Rule 702(a) through (d). (*See* Pls.' Opp. to Defs.' Mot. to Exclude Pls.' Experts (filed Oct. 3, 2022) (ECF No. 313) at 30-144 ("Pls.' Opp."); *see also* Decl. of Jeremy Mark Berg, Ph.D. Regarding Trial Testimony (Aug. 31, 2022) (ECF No. 297)) (summarizing qualifications and proposed testimony, and incorporating expert reports and curriculum vitae by reference).)

III. DR. WEI

Defendants have failed to show by a preponderance of the evidence that Dr. Wei's testimony meets the requirements of Rule 702. Dr. Wei has admitted that he failed to apply the statistical methodology he opines is necessary to evaluate the Madison Memory Study. (*Id.* at 18.) His testimony therefore is not based on sufficient facts or data under Rule 702(b) (*id.* at 20), and his opinion does not reflect a reliable application of the principles and methods to the facts of case under Rule 702(d). (*Id.* at 19.) (Pls.' Mem. of Law in Support of Their Mot. to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, & David Gortler (filed Sept. 1, 2022) (ECF 304) ("Pls.' MOL") at 17-18.) Thus, the Court should exclude Dr. Wei's testimony.

IV. DR. GOODMAN

The testimony of Dr. Goodman should be excluded under Rule 702 because Defendants have failed to show by a preponderance of the evidence that Dr. Goodman has the relevant expertise to assist the jury; his testimony lacks reliance on sufficient facts; and his opinion does not reflect reliable scientific principles to reason how apoaeguorin could have an effect on the body. (*Id.* at 29-34.) As a food allergy and safety expert, Dr. Goodman lacks the expertise under Rule 702(a) related to the absorption of non-allergenic proteins, like apoaeguorin, to opine on whether apoaeguorin could have an effect in humans. (*Id.* at 33.) In addition, Defendants have failed to show by preponderance of evidence how Dr. Goodman's testimony regarding potential mechanisms of action for Prevagen satisfies Rule 702(c), given that it relies on speculative reasoning rather than reliable scientific principles. Speculation on how apoaeguorin *might* theoretically work by drawing completely unsupported analogies to a distinct category of allergenic dietary proteins is not a scientific method or principle. (*Id.* at 30.)

V. DR. GORTLER

Defendants have failed to demonstrate by a preponderance of the evidence how Dr. Gortler's testimony meets the requirements of Rule 702 and it should be excluded in its entirety. (*Id.* at 34-42.)

First, Defendants have failed to demonstrate that it is more likely than not that Dr. Gortler's testimony will help the jury understand the evidence about apoaequorin under Rule 702(a) because Dr. Gortler's testimony focuses on drugs and substances other than apoaequorin and never ties those discussions to any property of apoaequorin. (*Id.* at 35.) Dr. Gortler concedes that he has not "done any clinical or analytical analyses whatsoever on apoaequorin, Prevagen, et cetera," and he does not point to any property of apoaequorin that would cause it to behave similarly to the substances he does discuss. (*Id.* at 35-36.) Further, as is the case for Dr. Goodman, *supra*, Dr. Gortler's speculative reasoning by analogy to other substances is not a reliable scientific methodology or principle that can satisfy the requirements of Rule 702(c). (*Id.*)

Similarly, Dr. Gortler's testimony regarding calcium's role in memory and Alzheimer's disease should be excluded because it involves assumptions that apoaequorin binds and reduces calcium in the brain. However, given that apoaequorin is unlikely to pass through the gastrointestinal tract intact, apoaequorin would not reach the brain and therefore would not have a therapeutic, calcium binding effect on brain. (Pls.' MOL at 37-38.) Dr. Gortler's opinion therefore fails to satisfy Rule 702(a) because it is irrelevant and will not help the jury. It also fails to satisfy Rule 702(c) because it is based on speculation and unsupported assumptions, not any reliable principle or method.

Dr. Gortler's proposed testimony regarding the purported active transport of apoaequorin

is entirely unreliable and outside his expertise or understanding. It should thus be excluded because it does not satisfy Rule 702(a), (c) and (d). (*Id.* at 39-41.)

Lastly, Defendants have failed to show by a preponderance of the evidence why Dr. Gortler's testimony regarding the safety of Prevagen meets the requirements of Rule 702(a), because Dr. Gortler's opinion that Prevagen is safe is not relevant to any issue in this case. (*Id.* at 41.)

VI. DRS. KURZER, SCHWARTZ, AND KATZ

Drs. Kurzer, Schwartz and Katz should all be precluded from testifying about potential mechanisms of action because their testimony is, like that of Drs. Gortler and Goodman, based entirely on different, and sometimes contradictory, speculative opinions about Prevagen's potential mechanism of action and thus do not satisfy Rule 702(a), (c), or (d). (Pls.' MOL at 42-47.)

CONCLUSION

The recent amendments to Rule 702 change nothing about the standard applied in the Court's December 19, 2022 Order (ECF No. 331). Plaintiffs have shown by well more than a preponderance of the evidence that Dr. Berg's qualifications and testimony meet the requirements under Rule 702.

On the other hand, as described above and in Plaintiffs' original Memorandum of Law, Defendants have failed to show by a preponderance of the evidence that their experts' testimony meets the standards of Rule 702 because it is based on speculation, unsupported assumptions, insufficient data, and flawed analogies to other substances. Hypothetical, completely unsupported theories about mechanisms of action applicable to other substances is not the reliable application of scientific principles and methods that Rule 702 requires. Defendants'

experts' testimony is inadmissible and should be excluded.

Dated: February 19, 2024

Respectfully submitted,

FEDERAL TRADE COMMISSION

By: /s/

ANNETTE SOBERATS
EDWARD GLENNON
ANDREW D. WONE
TIFFANY M. WOO
CHRISTINE LEE DELORME
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20850
202-326-2921, asoberats@ftc.gov
202-326-3126, eglennon@ftc.gov
202-326-2934, awone@ftc.gov
202-326-3583, twoo@ftc.gov
202-326-2095, cdelorme@ftc.gov
202-326-3259 (facsimile)

Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

PEOPLE OF THE STATE OF NEW YORK
BY LETITIA JAMES,

Attorney General of the State of New York

By: /s/

JANE M. AZIA
KATE MATUSCHAK
MARY ALESTRA
NOAH H. POPP
EMILY SMITH
Consumer Frauds and Protection Bureau
28 Liberty Street
New York, NY 10005
Tel: (212) 416-6189
212-416-6189, kate.matuschak@ag.ny.gov
212-416-6698, mary.alestra@ag.ny.gov
212-416-8915, noah.popp@ag.ny.gov
212-416-8316, emily.smith@ag.ny.gov
212-416-6003 (facsimile)

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of February, 2024, I have caused service of the foregoing Plaintiffs' Supplemental Memorandum of Law in Support of their Motion to Exclude the Testimony of Drs. Schwartz, Katz, Wei, Kurzer, Goodman, And Gortler, And In Opposition To Defendants' Motion To Exclude Dr. Berg to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: February 19, 2024

/s/ Kate Matuschak

Assistant Attorney General

New York State Office of the Attorney General